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### Interview

GBR interviewed Mr. Ajay Tandon Executive Director at Veeda

## VEEDA NEWS

### Frost & Sullivan recognizes Veeda Clinical Research as "The Indian Clinical Research Organization of the year 2019"

Award Recognizes Company's best practices, expertise & End-to-End Quality Clinical Research Solutions.

Veeda Clinical Research, India's leading independent CRO, has been awarded as the Indian Clinical Research Organization of the Year 2019 by Frost & Sullivan at India Best Practices Awards held on 16th October 2019 at Hyatt Regency, Mumbai, India.

The recipients of the annual Frost & Sullivan India Best Practices Awards were identified based on in-depth research conducted by Frost & Sullivan's analysts. The nominated companies were then evaluated on a variety of actual market performance indicators which include revenue growth; market share and growth in market share; leadership in product innovation; marketing strategy and business development strategy. Over the past several years, Veeda has differentiated itself by delivering innovative, flexible, high-quality, customer-driven solutions to become the leading CRO in India and has a track record for conducting specialized, complex, clinical trial projects.

While accepting the award, Mr. Ajay Tandon, Executive Director of Veeda said, "I sincerely thank Frost & Sullivan for nominating us for this award which recognizes the quality of our systems, processes, and people and our continuous effort in nurturing a quality-centric culture. I dedicate this award to our Founders, who from inception, have made quality and ethics the centre piece of our practices; to our Employees who bring our values to fruition each day; and to our Clients who continuously support and recognize us with repeat opportunities to service them."

**Read More :** <https://veedacr.com/2019/brochure/FS-PR.pdf>





## INDIAN PHARMA

### Govt releases guidelines for evaluation of Nano pharmaceuticals.

The Union Minister for Science & Technology, Earth Sciences and Health & Family Welfare, Dr. Harsh Vardhan has released "Guidelines for Evaluation of Nanopharmaceuticals in India", at an event in New Delhi recently.

**Read more :** <https://www.biospectrumindia.com/news/22/14992/govt-releases-guidelines-for-evaluation-of-nanopharmaceuticals.html>

Govt to bring all medical devices under CDSCO lens to improve safety & quality

The government plans to bring all medical devices, including implants and contraceptives, under the lens of the Central Drugs and Standard Control Organisation so as to improve their safety and quality.

**Read more :** <https://www.livemint.com/politics/policy/govt-to-bring-all-medical-devices-under-cdsc-lens-to-improve-safety-quality-11571412269232.html>

India-China Pharma Park in south China to open ample opportunities for Indian pharma companies to market their products

Ample opportunities are opened for Indian drug manufacturers to market their products in China with the establishment of an India-China Pharma Park in the soon-to-be developed Medical Pilot Zone in Fangchenggang in south China's Guang Xi province. Doors are opened for Indian companies to invest in the pilot zone.

**Read more :** <http://www.pharmabiz.com/NewsDetails.aspx?aid=118887&sid=1>

CDSCO urges pharma cos to submit stability studies as per New Drugs and Clinical Trials Rules

The Drugs Controller General of India (DCGI) in its circular stated, "Stability studies data is required to be submitted as per new drugs and clinical trials rules, 2019, which stipulates that when the application is for clinical trials only, the international non-proprietary name (INN) or generic name, drug category, dosage form and data supporting stability in the intended container closure system for the duration of the clinical trial is required".

**Read more :** <http://www.pharmabiz.com/NewsDetails.aspx?aid=118936&sid=1>

### Growing Indian pharma market needs more investment

New research from industry analyst GlobalData shows that the Indian pharmaceutical industry is set to grow from nearly \$31 billion at present, to around \$38 billion by 2022.

**Read more :** <https://www.thepharmaletter.com/article/growing-indian-pharma-market-needs-more-investment>



## REGULATORY

### WHO and IGBA Sign Agreement to Promote Biosimilars and Generics

The World Health Organization (WHO) and the International Generic and Biosimilar Medicines Association (IGBA), an umbrella organization with members including the Association for Accessible Medicines, Medicines for Europe, and a number of other national and regional generic and biosimilar organizations, have signed a memorandum of understanding.

**Read more:** <https://www.centerforbiosimilars.com/news/who-and-igba-sign-agreement-to-promote-biosimilars-and-generics>

### New guidelines being planned for streamlining recall of medicines

The government is planning to draft new guidelines to ensure its drug regulators can effectively recall substandard medicines released in the market here - in a move expected to improve the quality of drugs consumed by patients in the country.

**Read more :** <https://indianexpress.com/article/business/new-guidelines-being-planned-for-streamlining-recall-of-medicines-6056962/>

### FDA Finalizes Guidance on Streamlined IVD Reviews for Cancer Clinical Trials

As part of a push to reduce administrative burdens, the US Food and Drug Administration (FDA) on Wednesday finalized guidance on an optional streamlined submission process for determining the risk of an investigational in vitro diagnostic (IVD) in a clinical trial where an investigational IVD is being co-developed with an oncology investigational drug.

**Read more :** <https://www.raps.org/news-and-articles/news-articles/2019/10/fda-finalizes-guidance-on-streamlined-ivd-review-f>

## CDSCO adds another port for enhancing import of drugs

Through a recent Gazette notification, the apex drug regulatory body CDSCO has apprised about the addition of one more port.

**Read more :** <https://business.medicaldialogues.in/government-adds-another-port-for-enhancing-import-of-drugs/>

## India Plans to Bring All Medical Devices under CDSCO Oversight in December

The Indian government is planning to give the Central Drugs Standard Control Organization (CDSCO) oversight of the import, manufacture and sale of all medical devices in December. If finalized, the change would require many more medical device companies to seek certification and authorization.

**Read more :** <https://www.raps.org/news-and-articles/news-articles/2019/10/asia-regulatory-round-up-india-plans-to-bring-all>



## CLINICAL RESEARCH

Why many potential new cancer drugs are failing clinical trials

Even as cancer races to become the world's biggest killer, many of these seemingly effective drugs do not succeed in advancing to clinical use. They either turn out to be too toxic or just ineffective in humans.

**Read more :** <https://www.livemint.com/science/health/why-many-potential-new-cancer-drugs-are-failing-clinical-trials-11570555035304.html>

Emerging Technologies Set To Disrupt Clinical Trials

Disruptive Innovations, the annual conference sponsored by The Conference Forum, covers the full spectrum of clinical research with a focus on the innovators shaping the future of trials. Its goal is to bring together disruptive thinkers and change makers to discuss current solutions in clinical research and share ideas on how to transform drug development.

**Read more :** <https://www.clinalleader.com/doc/dpharm-emerging-technologies-set-to-disrupt-clinical-trials-001>

New strategy to treat Parkinson's disease

"This study highlights wild-type GCa6 activation as a potential therapeutic target for multiple forms of Parkinson's disease," said Krainc, who is chair of neurology and director of the Center for Neurogenetics at Northwestern University Feinberg School of Medicine

**Read more :** <https://www.worldpharmanews.com/research/4979-new-strategy-to-treat-parkinson-s-disease>

## Powerful new genomics method can be used to reveal the causes of rare genetic diseases

The team was focused on finding a better way to identify rare genetic diseases that emerge early in life and can be significantly debilitating or even life-threatening. Standard methods of sequencing genes and their transcripts - applied to the affected person and family members - usually can reveal the cause, but only if the disease-driving gene mutations are obvious ones that result in missing or severely truncated proteins.

**Read more :** <https://www.worldpharmanews.com/research/4973-powerful-new-genomics-method-can-be-used-to-reveal-the-causes-of-rare-genetic-diseases>

## Why European Biotechs Are Heading to Asia for Their Clinical Trials

As the region with the fastest-growing clinical activity, Asia is becoming increasingly attractive to European and North American biotechs. This progress in clinical trial activity is the result of a series of changes in the Asia-Pacific region in recent years. Since 2016, the clinical activity of biotech companies has increased by an average of 26% each year in the region.

**Read more :** <https://www.labiotech.eu/sponsored/european-biotechs-asia-pacific-clinical-trials/>



## FINANCIALS

**Mylan to invest \$1 billion in India on capex in 6 years**

Multinational drug company Mylan has said it will invest \$1 billion in the next 5-6 years on capex in India, given the importance of the country's position in world pharma supply-chain, and pitched for the government incentivising research and development activities.

**Read more :** <https://www.livemint.com/companies/news/mylan-to-invest-1-billion-in-india-on-capex-in-6-years-11569755400013.html>

**Indian pharma market sees growth of 11.5% in Q2FY20**

Led by seasonal factors and a stable growth of chronic segment, Indian pharmaceutical market (IPM) expanded 11.5 percent for the quarter ended September 30, according to market research firm AIOCD-AWACS.

**Read more :** <https://www.moneycontrol.com/news/business/indian-pharma-market-sees-growth-of-11-5-in-q2-fy20-4515591.html>

**Pharma R&D spend to stay low this year**

Research and development (R&D) spends of Indian pharma companies have been coming down since FY17 and are expected to remain low in FY20 as well due to challenging market conditions in the US.

**Read more :** <https://asianage.com/business/in-other-news/081019/pharma-rd-spend-to-stay-low-this-year.html>

## Prices of cancer, cardiac drugs may be slashed

In a departure from the usual practice, not all essential drugs will find their prices capped. The Standing National Committee on Medicines, which has been tasked with preparing the shortlist, will meet stakeholders on November 4 to consider their views before the National List of Essential Medicines (NLEM) 2019 is updated and finalised.

**Read more :** [http://economictimes.indiatimes.com/articleshow/71798680.cms?utm\\_source=contentofinterest&utm\\_medium=text&utm\\_campaign=cppst](http://economictimes.indiatimes.com/articleshow/71798680.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst)

## Online pharmacies to grow to \$3.7 billion by 2022: CLSA

The Indian pharma market is valued at \$20 billion and has been growing at 10-12 per cent. Continuation of current growth trends could propel the market to \$35 billion by 2025, the report noted.

**Read more :** [http://economictimes.indiatimes.com/articleshow/71650516.cms?utm\\_source=contentofinterest&utm\\_medium=text&utm\\_campaign=cppst](http://economictimes.indiatimes.com/articleshow/71650516.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst)



## MERGER AND AQUISITION

Sun Pharma Arm Acquires Remaining 3.04% Stake in PJSC Biosintez, Russia

Drug major Sun Pharmaceutical Industries on Monday said its Netherlands-based arm has fully acquired PJSC Biosintez, Russia by purchasing 3.04 per cent stake in the company under the mandatory tender offer.  
**Read more :** <https://www.indianweb2.com/2019/09/09/sun-pharma-arm-acquires-remaining-3-04-stake-pjsc-biosintez-russia/>

Strides acquires US capsule facility, set to invest further \$10m

Strides acquires the only FDA-approved integrated soft gel capsule manufacturing facility in the US, owned by Micelle, to support its operations in India.  
**Read more :** <https://www.in-pharmatechnologist.com/Article/2019/09/03/Strides-acquires-Micelle-facility-in-Florida>

Sweden's Sobi to Acquire Dova Pharmaceuticals

Swedish Orphan Biovitrum (Sobi) said it will snap up all outstanding shares of Dova for \$27.50 per share in cash. The offer was sweetened with the promise of a non-tradeable Contingent Value Right that entitles shareholders to an additional \$1.50 per share in cash upon regulatory approval of Doptelet (avatrombopag) for the treatment of chemotherapy-induced thrombocytopenia.  
**Read more :** <https://www.pharmalive.com/swedens-sobi-to-acquire-dova-pharmaceuticals-in-915-million-deal/>

## M&A Will Continue to Be a Mainstay for Growth in the Pharma Industry

For the past five years, there have been more than 400 mergers and acquisitions with companies in the gene therapy, immuno-oncology, microbiome and orphan drugs therapeutic space in North America and that trend is likely to continue, according to a new analysis.  
**Read more :** <https://www.biospace.com/article/big-m-and-a-deals-will-likely-continue-analyst-predicts/>

## 11 GI mergers & acquisitions

Here are 11 mergers and acquisitions that occurred this year in the gastroenterology space:  
**Read more :** <https://www.beckersasc.com/gastroenterology-and-endoscopy/11-gi-mergers-acquisitions.html>



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